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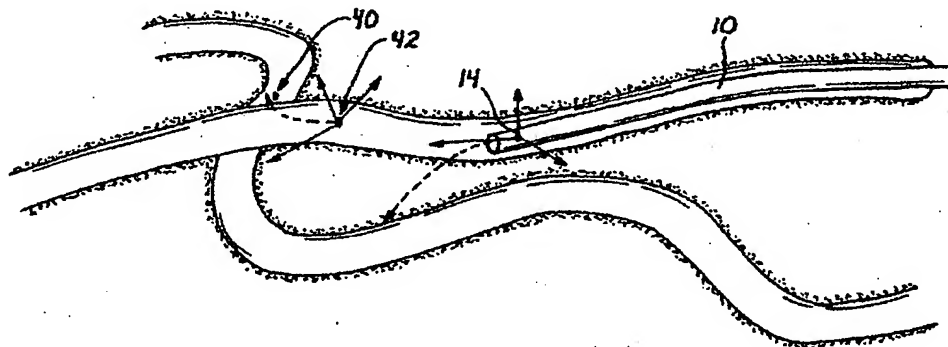
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(54) Title: METHODS AND APPARATUS FOR GUIDED TRANSLUMINAL INTERVENTIONS USING VESSEL WALL PEN-
ETRATING CATHETERS AND OTHER APPARATUS



(57) Abstract: Electro-anatomically navigated catheters (e.g., mapping catheters, tissue penetrating catheters, delivery catheters and/or sheaths) and associated methods whereby devices or substances may be delivered to specific locations within a patient's body and/or penetration tracts or passageways are formed at specific locations between anatomical structures. The catheters are equipped with sensors and a sensing field is created around the body of the patient. The sensor-equipped catheters are then inserted into the patient's body and the position of the catheter-mounted sensor(s) is/are observed on a display representing the sensing field. Apparatus may be included for propelling the catheter(s) to specific locations and/or specific rotation orientations, within the patient's body.

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**METHODS AND APPARATUS FOR GUIDED TRANSLUMINAL
INTERVENTIONS USING VESSEL WALL PENETRATING CATHETERS
AND OTHER APPARATUS**

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BACKGROUND

The prior art has included a number of electro-anatomical methods and apparatus for anatomical mapping of portions of a patient's body and/or for determining the position and rotational orientation of a catheter or probe within the patient's body. Examples of such prior art devices and methods include those described in United States Patent Nos. 5,647,361; 5,820,568; 5,730,128; 10 5,722,401; 5,578,007; 5,558,073; 5,465,717; 5,568,809; 5,694,945; 5,713,946; 5,729,129; 5,752,513; 5,833,608; 5,935,061; 5,931,818; 6,171,303; 5,931,818; 5,343,865; 5,425,370; 5,669,388; 6,015,414; 6,148,823 and 6,176,829.

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SUMMARY OF THE INVENTION

In accordance with the present invention, there are provided a) vessel wall penetrating catheters and apparatus that are passable through or used in conjunction with vessel wall penetrating catheters, b) catheters useable to deliver 20 radially expandable apparatus (e.g., connectors, stents, stent-grafts, occlusive blockers, etc.), c) other devices useable to perform the PICVA, PICAB, substance delivery or any of the other procedures disclosed and claimed in United States Patents Nos. 5,830,222, 6,068,638 and 6,071,292 or copending United States Patent Application Nos. 08/730,327, 09/056,589, 09/282,276 and 09/282,774, 25 equipped with sensors that are useable in conjunction with other extracorporeally located apparatus to guide the three-dimensional positioning and/or rotational orientation of such catheters and devices within the bodies of human or animal patients. Additionally, there are provided methods of using these sensor-equipped catheters to penetrate from a location within the lumen of a blood 30 vessel or other anatomical structure to a target location (e.g., the lumen of another blood vessel or luminal anatomical structure, other locations on the same blood vessel or luminal anatomical structure, a tumor, an aberrant anatomical structure or malformation, site(s) at which drugs or other substances

are to be deposited, site(s) at which apparatus (e.g., electrodes, sensors, etc.) are to be deposited, and /or site(s) from which tissue or fluid (e.g., tissue biopsies, blood samples, other body fluid samples, ova, etc) are to be harvested or obtained).

5 Further in accordance with this invention, there is provided a sensor-equipped vessel wall penetrating catheter device that generally comprises a) a catheter, b) a penetrator that is advanceable from the catheter to penetrate outwardly through the wall of a vessel or anatomical conduit in which the catheter is positioned and to a target location and c) at least one sensor
10 mounted on or in the catheter. These sensor-equipped vessel wall penetrating catheters are inserted into the body of a patient and one or more energy-field-creating apparatus (e.g., magnet(s), ultrasound generator(s), light source(s), radiofrequency generator(s), x-ray machine(s), infrared source(s), microcurrent source(s), etc.)) are used to create electromagnetic fields or other energy field
15 (i.e. "Sensing fields") around and/or within the patient's body. A sensor-monitoring and indicia-providing means (e.g., a computer/controller and monitor) is then used to receive signals from the sensor(s) and to provide, on the basis of those signals, indicia of the position and/or rotational orientation of each sensor within the sensing field. In some applications, the specific anatomy of all
20 or a portion of the patients body may be mapped using known techniques such as tomographic imaging techniques. Such anatomical mapping data is provided to a computer along with signal(s) received from the sensor(s) mounted on or in the vessel wall penetrating catheter. The computer is programmed to determine the precise location and/or orientation of the sensor(s) within the anatomically
25 mapped region(s) of the patient's body, using the anatomical mapping data and sensor signals provided to the computer. In this manner, the sensor-equipped vessel wall penetrating catheter may be inserted into the patient's body and advanced into an anatomically-mapped area of interest. The electromagnetic field(s) or other energy is then actuated and the signal(s) from the catheter-mounted sensor(s) is/are received by the computer. The computer then
30 provides an image or other indication of the precise longitudinal position and rotational orientation of the sensor-equipped vessel wall penetrating catheter,

within the patient's body. In this manner the catheter may be precisely positioned and rotationally oriented so that, when the penetrator is advanced from the catheter, the penetrator will penetrate to the intended target location. Specific examples of sensors, sensor-monitoring and indicia-providing means (including and in addition to the computer) and energy-field creating apparatus and related software and methodology useable in this invention are described in United States Patent No. 5,833,608 (Acker) entitled "Magnetic Determination of Position and Orientation as well as other United States Patent Nos. 5,647,361; 5,820,568; 5,730,128; 5,722,401; 5,578,007; 5,558,073; 5,465,717; 5,568,809; 5,694,945; 5,713,946; 5,729,129; 5,752,513; 5,833,608; 5,935,061; 5,931,818; 6,171,303; 5,931,818; 5,343,865; 5,425,370; 5,669,388; 6,015,414; 6,148,823 and 6,176,829, the entireties of which are expressly incorporated herein by reference.

Further in accordance with this invention, there are provided methods wherein the above-summarized sensor-equipped vessel wall penetrating catheter is used to penetrate from a position within the lumen of a blood vessel, other type of luminal anatomical structure or conduit (e.g., ureter, fallopian tube), outwardly through the wall of the vessel or conduit in which the vessel-wall penetrating catheter is positioned, and to a target location (e.g., another blood vessel or luminal anatomical structure, other locations on the same blood vessel or luminal anatomical structure, tumors, aberrant anatomical structures or malformations, site(s) at which drugs or other substances are to be deposited, site(s) at which apparatus (e.g., electrodes, sensors, etc.) are to be deposited, and /or sites from which tissue or fluid (e.g., tissue biopsies, blood samples, other body fluid samples, ova, etc) are to be harvested or obtained).

Further in accordance with this invention, there is provided a sensor-equipped delivery catheter for navigated delivery of a radially expandable implantable device, such as a stent, a stent-graft, a tube graft, an embolic blocker such as those described in United States Patent Application Nos. 08/730,327, 09/117,516 and 09/613,675 the entireties of which are expressly incorporated herein by reference or a connector device useable for connecting two blood vessels in which openings have been formed, as described in United

States Patent Application Nos. 08/730,327; 09/117,515; 09/117,520; 09/267,943; 08/868,307 and 08/970,694, the entireties of which are expressly incorporated herein by reference. These sensor-equipped delivery catheters of the present invention generally comprise a) a catheter, b) a radially expandable implantable device mounted on or in the catheter and c) at least one sensor mounted on or in the catheter. These sensor-equipped delivery catheters are inserted into the body of a patient and one or more energy-field-creating apparatus (e.g., magnet(s), ultrasound generator(s), light source(s), radiofrequency generator(s), x-ray machine(s), etc.)) are used to create electromagnetic fields or other energy field (i.e. "sensing fields") around and/or within the patient's body. A sensor-monitoring and indicia-providing means (e.g., a computer/controller and monitor) is then used to receive signals from the sensor(s) and to provide, on the basis of those signals, indicia of the position and/or rotational orientation of each sensor within the sensing field. In some applications, the specific anatomy of all or a portion of the patients body may be mapped using known techniques such as tomographic imaging techniques. Such anatomical mapping data is provided to a computer along with signal(s) received from the sensor(s) mounted on or in the vessel wall penetrating catheter. The computer is programmed to determine the precise location and/or orientation of the sensor(s) within the anatomically mapped region(s) of the patient's body, using the anatomical mapping data and sensor signals provided to the computer. In this manner, the sensor-equipped delivery catheter may be inserted into the patient's body and advanced into an anatomically-mapped area of interest. The electromagnetic field(s) or other sensing field is then actuated and the signal(s) from the catheter-mounted sensor(s) is/are received by the computer. The computer then provides an image or other indication of the precise longitudinal position and rotational orientation of the sensor-equipped delivery catheter, within the patient's body. In this manner, the operator may precisely position and rotationally orient the delivery catheter so that subsequent deployment and release of the radially expandable implantable device from the catheter will result in implantation of the device at the intended implantation site and/or in an intended rotational orientation. Specific examples of sensors,

sensor-monitoring and indicia-providing means (including and in addition to the computer) and energy-field creating apparatus and related software and methodology useable in this invention are described in United States Patent No. 5,833,608 (Acker) entitled "Magnetic Determination of Position and Orientation
5 as well as other United States Patent Nos. 5,647,361; 5,820,568; 5,730,128; 5,722,401; 5,578,007; 5,558,073; 5,465,717; 5,568,809; 5,694,945; 5,713,946; 5,729,129; 5,752,513; 5,833,608; 5,935,061; 5,931,818; 6,171,303; 5,931,818; 5,343,865; 5,425,370; 5,669,388; 6,015,414; 6,148,823 and 6,176,829, the entireties of which are expressly incorporated herein by reference.

10 Further in accordance with this invention, there are provided methods wherein the above-summarized sensor-equipped delivery catheter is used to deliver a radially expandable implantable device to a specific location and in a specific rotational orientation within a human or veterinary patient's body.

15 Still further in accordance with the invention, the "sensing field" may further operate as a propulsion field whereby certain components of the field are controlled in a manner that propels or moves a sensor-equipped vessel penetrating catheter, a sensor equipped delivery catheter, an accompanying guidewire and/or portions thereof (e.g., the penetrator of the vessel wall penetrating catheter) through the patient's body to a specific target site and/or
20 in specific rotational orientation(s).

Still further in accordance with the invention, the sensor(s) mounted on or in the above-summarized vessel penetrating catheter and/or delivery catheter may be replaced by, or may function as an emitter or transmitter rather than a sensing and the sensing field generating apparatus maybe replaced by
25 apparatus for detecting those transmitter(s) or receiver(s). Such detecting apparatus may be positioned at several locations around or in the patient's body such that the precise 3 dimensional position and/or rotational orientation of each catheter-mounted emitter or transmitter may be computed.

30 Further objects, aspects and elements of this invention will be apparent to those of skill in the art upon reading and understanding the detailed description and examples set forth herebelow and in the accompanying drawings and/or appended documents.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a schematic diagram of a method of the present invention where a sensor-equipped vessel wall penetrating catheter and a sensor-equipped mapping catheter are used to perform a percutaneous, catheter-based, coronary artery bypass procedure in which a tubular graft is placed between the left internal mammary artery LIMA and an obstructed coronary artery.

Figure 2 is a partial, sectional view of a first embodiment of a sensor-equipped mapping catheter according to this invention.

Figure 2a is a partial, sectional view of a second embodiment of a sensor-equipped mapping catheter according to this invention.

Figure 3 is a partial, sectional view of a first embodiment of a sensor-equipped tissue penetrating catheter according to this invention.

Figure 3a is a partial, sectional view of a second embodiment of a sensor-equipped tissue penetrating catheter according to this invention.

Figure 3a' is a cross sectional view through line 3a'-3a' of Figure 3a.

Figure 3b is a partial, sectional view of a third embodiment of a sensor-equipped tissue penetrating catheter according to this invention, which includes an IVUS imaging transducer.

Figure 4 is a schematic diagram of a double coronary artery bypass procedure according to this invention, wherein one tubular bypass graft is placed to connect left internal mammary artery to the left anterior descending coronary artery and a second tubular bypass graft is placed to connect the descending aorta to the right coronary artery.

Figure 5 is a schematic diagram of a sensor that comprises first, second and third electromagnetic coils arranged in a generally triangular configuration.

Figure 6 is a schematic diagram showing the result of a percutaneous in situ coronary venous arterialization (PICVA™) procedure performed using sensor-equipped catheter(s) of the present invention.

Figure 7 is a schematic diagram illustrating one way in which the percutaneous in situ coronary venous arterialization (PICVA™) procedure of Figure 6 may be performed.

Figure 8 is a diagram showing one type of visual monitor display that may be provided to permit the operator to visualize the position of a sensor-equipped tissue penetrating catheter during a procedure wherein the penetrating catheter is used to penetrate from the lumen of a first blood vessel to a target location.

Figure 9 is a partial sectional view of a sensor-equipped connector delivery catheter of this invention with a radially expandable connector device positioned within the delivery catheter.

Figure 10 is a diagram of two adjacent blood vessels having a bloodflow passageway formed therebetween and a partially covered, flow-directing connector device implanted by the sensor-equipped sensor delivery catheter of Figure 9.

Figure 11 is a partial cut-away view of an embodiment of a sensor-equipped tissue penetrating catheter according to this invention.

Figure 12 is a perspective view of a sensor-equipped sheath having an anchorable distal end and a side opening.

Figure 12a is an enlarged, partially sectional view of the distal portion of the sensor-equipped sheath of Figure 12/

Figure 12b is a cross sectional view through line 12b-12b of Figure 12.

Figure 12c is a cross sectional view of a non-rotatable tissue penetrating catheter that is insertable into and engageable with the non-round lumen of the sensor-equipped sheath of Figures 12, 12a and 12b.

DETAILED DESCRIPTION OF EXEMPLARY EMBODIMENTS

In some embodiments, electromagnetic fields may be used to accomplish the desired catheter guidance and anatomical mapping. One example of an electromagnetic catheter guidance and positioning system that may be incorporated into the present invention is the Carto™ or NOGA™ system available from Biosense-Webster, Inc., a Johnson & Johnson Company, Diamond Bar, California and described in a number of patents, including United States Patent No. 5,833,608 (Acker) entitled "Magnetic Determination of Position and Orientation. In these systems, magnet(s) (e.g., electromagnetic coils) are

positioned and used to generate a plurality of different magnetic fields around the patient. Each magnet has at least one non-zero component of known magnitude which is quasilinear (i.e., constant, linear, or nearly linear) with respect to distance in a certain reference direction and within a sensing volume.

5 A controller, such as a microprocessor or computer, is connected to the magnet(s) and is operative to actuate the magnet(s) in a fashion that generates different magnetic fields in a preselected sequence. At least one sensor is mounted in a fixed position on or in the catheter (tissue penetrating catheter or catheter for delivering radially expandable blocker, connector, stent, stent-graft,

10 etc) and the catheter is moved within the sensing volume (e.g., an anatomical region wherein the sensing is to be conducted). The catheter-mounted sensor(s) may be very small in size and preferably are of solid-state design. Each sensor detects magnetic field components in at least two different, preferably orthogonal, local directions relative to that sensor. Desirably, the sensor(s) is/are

15 arranged to detect magnetic field components in three different, desirably orthogonal, local directions relative to the sensor(s) so as to determine the position of the catheter in three dimensions. These local directions are directions in the frame of reference of the sensor, and may differ from the reference directions of the magnet(s) used to create the magnetic field(s) around the

20 patient's body. A calculator device, such as a computer, receives signals or other indicia of the magnetic field components detected by each sensor. This calculator device then computes the position and/or rotational orientation of each sensor relative to the magnet(s) on the basis of the magnetic field components that are detected by the sensor(s), while the magnets are operated to generate

25 the various magnetic fields. Because the fields within the sensing volume are quasilinear, as defined above, measurable magnetic fields and rates of variation in field component magnitudes per unit distance can be determined throughout a relatively large sensing volume (e.g., a volume having dimensions of about 30 cm or more) even in instances where the maximum field is relatively low. In this

30 manner, the apparatus can accurately monitor the rotational orientation and position of the sensor-equipped catheter as it is inserted or advanced into the body of a human or animal patient.

In many applications, the magnet(s) will generate a) a first substantially uniform magnetic field in a first reference direction within a sensing volume and b) at least a second substantially uniform magnetic field in another reference direction within the sensing volume (e.g., a "second" reference direction that is different from the first reference direction). Preferably, the second reference direction is orthogonal to the first reference direction. The magnet(s) may also generate gradient fields within the sensing volume (e.g., first and second gradient fields), such gradient fields having differing predetermined patterns of variation in the different reference directions (e.g., first and second reference directions) within the sensing volume.

Preferably, the magnet(s) may also be operable to generate a field such that a component of the field varies with a predetermined pattern of variation in a third reference direction, different from, and preferably orthogonal to, the first and second reference directions, and the calculation apparatus is arranged or programmed to determine the position of the sensor-equipped catheter in the third direction, as well as in the first and second directions. The component varying in the third direction may be provided as a part of a third gradient field different from the first and second gradient fields and from the uniform fields. Alternatively, the component varying in the third direction may be provided in the first gradient field, second gradient field or both. The magnet(s) may also be arranged to generate a third uniform field in the third reference direction.

Also, the magnets may be employed in sets, each such set including a pair of field-directing elements disposed on opposite sides of the sensing volume. The field-directing elements may be arranged to direct flux codirectionally with one another to provide a substantially uniform field in the sensing volume and to direct flux counter-directionally to one another to provide a gradient field in the sensing volume. The field-directing elements of each such pair desirably are electrically conductive coils, most preferably Helmholtz coils disposed substantially coaxially with one another so that the axis of each such pair extends in one of the reference directions.

Apparatus according to a further aspect of the invention includes a magnet structure including at least one, and in some embodiments preferably

two, pair(s) of Helmholtz coils, the coils of each such pair being substantially coaxial with one another and defining a pair axis. The coils of each such pair are disposed on opposite sides of a sensing volume so that the coil axes of the various pairs are substantially orthogonal to one another. The apparatus further
5 includes a controller (e.g., a microprocessor controller or computer) which sends actuation signals to actuate each pair of Helmholtz coils. Such actuation results in a homogeneous-field state with codirectional current flow around the pair axis in both coils of the pair to thereby generate a magnetic field directed parallel to the axis of that pair, such magnetic field having substantially uniform strength
10 within the sensing volume. The controller may also be operative to actuate each pair of Helmholtz coils in a gradient field state with counterdirectional current flow in the coils of the pair, thereby resulting in a magnetic field that has a component directed parallel to the axis of the pair, such magnetic field component having a substantially linear gradient of magnitude in the sensing volume. The
15 controller may be operative to cause the pairs of coils to be actuated to different states according to a preselected time sequence, typically with only one pair actuated to only one state at any given time. Apparatus according to this aspect of the invention preferably also include a sensor-equipped catheter of the present invention that is moveable within the sensing volume (e.g., within the
20 patient's thorax), the catheter-mounted sensor being capable of measuring magnetic field components in at least two, and preferably three, mutually orthogonal local directions relative to the sensor. In this way, the catheter-mounted sensor can measure homogeneous-field local components in the local directions while the coil pairs are in the aforementioned homogeneous-field
25 states while also measuring gradient-field local components in the local directions relative to the sensor while the coil pairs are in the aforementioned gradient field states.

The apparatus may further include apparatus for displaying an image of a portion of the patient's body (e.g., the sensing volume) obtained by an imaging
30 technique (e.g., a tomographically generated CT image through the patient's heart or thorax) on a monitor or display along with a representation of the sensor-equipped catheter superposed thereon. The monitor display may further

be adapted to accept and display body image data representing the body image in a body image frame of reference different from the frame of reference defined by the reference directions of the magnet means and/or relationship data representing the relationship between the body image frame of reference and the magnet means frame of reference. The system may further be adapted to transform the position of the sensor-equipped catheter within the magnet's frame of reference, the body image data or both, so as to provide the catheter position data and the body image data in a common frame of reference. The apparatus may also incorporate one or more fiducial markers, and means for attaching each such fiducial marker to the patient's body so that the above described superimposed images may include an image of each fiducial marker. The apparatus may further include apparatus for determining the position of each fiducial marker in the magnet's frame of reference. In this regard, each fiducial marker may include a sensor for measuring the magnetic field components, and the calculator apparatus may be arranged or programmed to determine the position and orientation of each fiducial marker from the magnetic fields measured by the sensors of the fiducial markers. In such embodiments, the relationship data may include data regarding the difference, if any, between the position and orientation of each fiducial marker as derived from magnetic field measurements and the position and orientation of the fiducial marker as shown in the image data.

The system is capable of determining not only the three-dimensional position, but also the rotational orientation, of each catheter-mounted sensor located within a patient's body. To detect the rotational orientation of a particular sensor, a plurality of magnetic fields are generated, each including one or more quasilinear components as discussed above. Desirably, the plural magnetic fields include first and second homogeneous magnetic fields, each of which has a non-zero component of substantially uniform magnitude throughout the sensing volume in first and second reference directions and further includes first and second gradient fields having components which vary in predetermined patterns of variation. As discussed above in connection with the apparatus, a sensor disposed within the sensing volume measures magnetic field

components in at least two, and preferably three, different local directions relative to the sensor during application of each of these fields. In this manner, the specific rotational orientation of the catheter relative to the reference directions of the homogeneous-fields is determined from the homogeneous-field local components measured by the sensor during application of the homogeneous fields. Additionally, the position of the catheter in the reference directions (i.e., a three-dimensional determination when three reference directions are provided) is determined from the homogeneous field local components and from the gradient field local components measured during application of the first and second gradient fields.

Prior to or during the procedure, the generation of all fields by the magnet(s) may be stopped one or more times and, while such magnetic field generation is stopped, the catheter-mounted sensor(s) may be actuated to detect baseline magnetic field components, such as from the earth's magnetic field, stray magnetic sources and the like. This baseline magnetic field component data can then be used to correct the magnetic field component data acquired by the catheter-mounted sensors during the procedure. In some applications, an image of the sensor-equipped catheter may be superposed on a standard or cross-sectional anatomical image, such as an image obtained by X-ray, MRI or CT scan.

In some applications, it may be desired to place sensor(s) at target anatomical location(s) within the mapped anatomy of the patient, in addition to the provision of sensor(s) mounted on the operative catheter. In this manner, the electro-anatomical mapping and guidance system may be used to guide the precise positioning of the operative catheter-mounted sensor(s) relative to the target sensor(s). As described more fully herebelow, the use of one or more target sensor(s) in addition to the sensor(s) mounted on the operative catheter may be particularly useful when it is desired to advance a penetrator or other member from an operative catheter positioned in a relatively stable anatomical structure (e.g., the internal mammary artery or aorta) to a target site located on an anatomical structure that is moving (e.g., a coronary artery or coronary vein located on the beating heart).

A further aspect of the invention provides a method of depicting, on a monitor screen or display, the precise position and/or rotational orientation of a sensor-equipped catheter of the present invention within a previously imaged or mapped anatomical region of the patient's body. Methods according to this aspect of the invention include the steps of providing a sensor in a substantially fixed position relative to the catheter and acquiring an image of the catheter while the catheter is in a first orientation. The method further includes the step of monitoring the orientation of the sensor-equipped catheter by monitoring magnetic fields transmitted to or from the sensor-equipped catheter, to thereby monitor the orientation of the catheter when the catheter is in a moved orientation different from the first orientation. The method further includes the step of transforming the image of the catheter in the first orientation into an image of the catheter in its moved orientation and displaying the transformed image. Preferably, the monitoring, transforming and displaying steps are repeated as the catheter is moved through a range of moved orientations so that a transformed image corresponding to each such moved orientation is displayed substantially in real time when the catheter is in such moved orientation.

The method may be performed with a plurality of catheters simultaneously. Thus, separate sensors may be affixed to each of a plurality of catheters, and the steps of acquiring an image of the catheter may include the step of acquiring the images of all of the catheters in respective first positions. The steps of monitoring the orientation of the sensor and determining the orientation of the catheter may include the step of monitoring the orientation of all of the sensors and determining separate moved orientations for each catheter. The step of transforming the image may include the step of transforming the image of each catheter into an image of that catheter in its respective moved orientation. The displaying step may be conducted so as to display all of the transformed images together, so that the orientations of the transformed images relative to one another correspond to the orientations of the catheters relative to one another. For example, where the catheters are the bones connected to one another at a skeletal joint, the physician can observe the transformed images of the bones, and thus observe the relative orientations

of the catheters constituting the joint during a medical procedure without taking additional x-rays as the bones are moved.

Preferably, the method includes the step of determining the position of each sensor in a fixed frame of reference while the catheters are in their respective starting orientations and while the catheters are in the respective moved orientations, so that the steps of transforming and displaying the images may include the step of adjusting the positions of the displayed transformed images relative to one another to compensate for relative movement of the catheters. Thus, the displayed images will correctly represent the positions of the catheters relative to one another.

Yet another aspect of the invention includes methods of mapping physiologic variables within the body of a living subject. A method according to this aspect of the invention desirably includes the steps of placing a sensor-equipped catheter in or on the body, sensing a physiologic variable by way of a transducer element located on the catheter and determining the position of the catheter by monitoring magnetic fields directed to or from a magnetic field sensor on the sensor-equipped catheter to thereby provide a measurement of the physiologic variable associated with a position. Most preferably, methods according to this aspect of the invention include the further steps of repeating the aforesaid steps to provide a plurality of measurements associated with a plurality of positions, to thereby provide a map of the physiologic variable over a plurality of positions. The method may further include the step of displaying such map as a visible image as, for example, as a set of contour lines, areas of different color or areas of differing contrast, with or without other features derived from other imaging modalities. For example, a map of body temperature, oxygen level or other physiologic variable can be overlaid on an MRI, CAT or similar image.

Still further aspects of the invention provide apparatus for generating one or more magnetic fields in a field frame of reference so that at least one of those magnetic fields includes at least one non-zero parameter, such non-zero parameter being quasilinear with respect to distance from point to point within the field frame of reference. The apparatus according to this aspect of the invention may further comprise a catheter adapted for disposition within the

patient's body, a sensor mounted on that catheter for monitoring the magnetic field prevailing at the sensor-equipped catheter while the sensor-equipped catheter is disposed in the patient's body and for sending a signal representing at least one parameter of the so-monitored field. Additionally, there may be
5 included a calculator apparatus for determining the position of the sensor-equipped catheter in the field frame of reference from the signal provided by the field sensor. The apparatus may also be capable of displaying an image of the patient's body along with a superimposed representation of the catheter so that the representation of the catheter appears on the displayed image at a location
10 on the body image that conforms to the catheter position data provided by the calculator apparatus. Still further aspects of the invention include methods of operating the sensor-equipped vessel wall penetrating catheter, the sensor equipped delivery catheter for radially expandable apparatus and the other apparatus energy field generating and controlling apparatus (e.g., magnets,
15 computer, calculator, controller, monitor/display) to accomplish navigated positioning and orientation of the sensor equipped catheter(s) within the patient's body. Specific examples of revascularization methods that use this invention are shown in Figures 1,4,6,7 and 8 and are fully described herebelow.

In embodiments where electromagnetic fields are used, the sensor(s)
20 mounted on or in the catheter(s) may comprise a sheetlike support and a plurality of magnetically sensitive elements, each having a preselected sensitive direction, disposed on the support. The support may be folded so that the magnetically sensitive elements are non-coplanar. The support may incorporate a rectangular or square central panel with two side panels , a tip panel and an
25 elongated strip all extending from different edges of the central panel to form a generally cruciform shape. The sensitive elements may be mounted on the various panels, and the panels may be folded over a dielectric core. The sensor most preferably incorporates a physiologic sensing element sensitive to a physiologic variable, this sensing element being attached to the same support
30 as the magnetically sensitive elements. One specific sensor design that is particularly useful for over-the-wire type catheters is shown in Figure 5 and described fully herebelow.

Referring now to the accompanying Figures 1-11, there are shown specific embodiments of the invention which serve as examples of the present inventive concept.

*Procedures Using A Sensor-Equipped Mapping Catheter And A
5 Sensor Equipped Tissue Penetrating Catheter*

Figure 1 illustrates a method for using a vessel wall penetrating catheter 10 that is equipped with a magnetic field component sensor 14 and a mapping catheter 12 that is also equipped with a magnetic field component sensor 16, to perform a percutaneous, catheter-based, coronary artery bypass procedure
10 wherein a tubular graft is placed between the left internal mammary artery LIMA and an obstructed coronary artery, distal to an obstruction OB, thereby allowing arterial blood from the LIMA to flow into the coronary artery, distal to the obstruction OB.

In this example, a preliminary tomographic scan or imaging study need
15 not have been performed because two (2) separate sensors 14, 16 are employed to accomplish real-time, continuous sensing of the precise positions of both the vessel wall penetrating catheter 10 positioned in the LIMA and the mapping catheter 16 positioned in the obstructed coronary artery. Initially, electromagnetic coils are placed at positioned outside of the patient's body and
20 are utilized to form electromagnetic fields, as described here above. The vessel wall penetrating catheter 10 incorporating a first magnetic sensor 14 is inserted into the patient's arterial vasculature and is advanced into the left internal mammary artery LIMA. The first sensor 14 is actuated as the vessel wall penetrating catheter 10 is advanced through the LIMA, thereby allowing the
25 computer to accurately map the anatomy of the LIMA. The mapping catheter 12 is also inserted into the patient's arterial vasculature and advanced into the obstructed coronary artery and through the obstruction OB. With its magnetic sensor 16 actuated, the mapping catheter is advanced through the portion of the coronary artery distal to the obstruction, thereby providing to the computer
30 accurate mapping data of the coronary artery. The computer then displays on a monitor screen a depiction of each blood vessel in each catheter. The three-dimensional sensor 14 of the being vessel wall penetrating catheter 10 is

specifically mounted in fixed orientation relative to the direction in which gave long penetrator needle will advance out of and away from the catheter 10, as indicated by the dotted line labeled "long needle path." Also, a being sensor 16 mounted in the mapping catheter may be the positioned in the precise location in the coronary artery, distal to the obstruction OB, into which the graft is intended to enter. Thereafter, watching the monitor screen, the operator can rotate the vessel wall penetrating catheter 10 into a specific rotational orientation which ensures that, when he long penetrator needle is subsequently advanced, it will penetrate outwardly through the wall of the LIMA a that the location from which the bypass graft is intended to and the eighth, through the thoracic cavity and through the wall of the coronary artery into the lumen of the coronary artery immediately adjacent the position of the sensor 16 of the mapping catheter 12. With the catheter so positioned and oriented, the penetrator is then advanced in the above described manner and a guidewire is then advanced through a lumen of the penetrator and into the lumen of the coronary artery. The penetrator is then retracted into the vessel wall penetrating catheter 10, leaving the guidewire extending from the lumen of the L IMA, through the opening formed in the wall of the LIMA, through the thoracic cavity, through the opening formed in the wall of the coronary artery distal to the obstruction OB and into the on obstructed distal portion of the coronary artery lumen. Thereafter, the vessel wall penetrating catheter 10 may be extracted and a flexible tube graft may be advanced over the guidewire and the opposite ends of the tube graft may be attached to the LIMA and coronary artery. Arterial blood may then flow out of the lumen of the LIMA, through the opening formed in the wall of the LIMA, through the tube graft, through the opening formed in the wall of the coronary artery and into the lumen of the coronary artery distal to the obstruction OB, thereby accomplishing the desired bypass of the coronary artery obstruction OB.

Sensor Equipped Catheters

Figures 2, 2a, 3, 3a, 3a', 3b and 11 show details of the construction of an exemplary sensor-equipped mapping catheter 10a and an exemplary sensor-equipped vessel wall penetrating catheters 10b, 10c, 10d, 10e. The vessel wall penetrating catheter 10b, 10c, 10d, 10e may incorporate or include any or all

over the elements of the vessel wall catheters described in United States Patent Nos. 5,830,222; 6,068,638; 6,159,225 or 6,071,292 or in co-pending United States Patent Application Nos. 08/730,324; 09/117,515; 08/837,295; 09/059,532; 08/837,294, 09/056,589; 09/282,276; 09/282,774; 09/507,139; 09/505,149 and/or 09/766,502, the entirety of each such patent and patent application being expressly incorporated herein by reference. Additionally, the vessel wall penetrating catheter 10b, 10c, 10d, 10e comprises a magnetic field component sensor 14 stick simply mounted on the catheter body and at a specific longitudinal location and in specific rotational or radial relationship to be outlet opening 18 and through which the penetrator 20 exits the catheter body. This magnetic field component sensor 14 preferably comprises a plurality of magnetic coils arranged in orthogonal relationship to one another, which is expressly incorporated herein by reference. In embodiments where the vessel wall penetrating catheter 10b, 10c, 10d, 10e is desired to have a guidewire lumen 22 as shown in Figure 11, the guidewire lumen 22 may pass through the catheter body adjacent to or side-by-side with the sensor 14, as shown in Figure 11. However, in other embodiments it may be desirable for the guidewire lumen to pass longitudinally through the sensor of the catheter body and for the orthogonally positioned components of the sensor 14 to be disposed about to the guidewire lumen, as shown in Figure 5. Specifically, Figure 5 illustrates a sensor 14a that comprises a first 30, second 32 and third 34 electromagnetic coils. These three coils 30, 32, 34 are attached to one another in a generally triangular configuration such that the guidewire lumen 22 passes through the sensor of the coils and is substantially centered within the sensor 14a.

Figure 2 shows a sensor-equipped mapping catheter 10a which comprises an elongate, flexible catheter body 17 and a sensor 14 of the above described type mounted on or in the catheter body 17. An optional centering balloon 15 may be provided to center the mapping catheter 10a within the lumen of a blood vessel. Such centering of the catheter may be particularly desirable in applications where the vessel being mapped is substantially larger in diameter than the mapping catheter 10a and, thus, it is desirable to prevent the mapping catheter from undergoing side-to-side movement as the mapping procedure

proceeds. In embodiments where the optional centering balloon 15 is used, the balloon 15 may be inflated to a size that is close to the luminal diameter of the blood vessel but does not frictionally coapt with the blood vessel wall so firmly that the operator is prevented from longitudinally advancing or retracting the mapping catheter 10a during the mapping procedure.

Figure 2a shows another embodiment of a mapping catheter 10b which comprises an elongate, flexible catheter body 17 and a sensor 14 of the above described type mounted on or in the catheter body 117. A retractable sheath 43 is positioned around the catheter body 17. A plurality of centering arms 45 are attached at radially spaced apart locations around the body of the catheter 17. When the sheath 43 is advanced distally it will compress the centering arms to straight configurations and will constrain or hold the centering arms against the outer surface of the catheter body 17. When the sheath 43 is retracted, as shown in Figure 2a, the centering arms 45 will spring outwardly and will assume their curved configurations. In this manner, the centering arms 45 will ride against the luminal wall of the vessel as the catheter 10a is advanced or retracted, thereby maintaining the sensor 14 in a substantially centered position within the vessel lumen and eliminating variability in the vessel mapping that can result from lateral or side-to-side movement of the sensor 14 within the vessel lumen.

Figures 3-3b show several different examples of sensor-equipped tissue penetrating catheters of this invention. In the example of Figure 3, the sensor 14 is mounted within the catheter, near the penetrator outlet aperture 18, but is not attached to the penetrator housing.

In the example of Figure 3a and 3a' the sensor 14 is mounted within the catheter proximal to the penetrator outlet aperture 18 and is affixed to a penetrator housing 9 by way of a stabilizer 27. The penetrator housing 9 is formed of a rigid material such as metal, and the stabilizer 27 securely attaches the sensor 14 to the housing 9. As shown in the cross sectional view of Figure 3a', the stabilizer 27 may be specifically configured to firmly clamp or hold the sensor 14 a fixed distance from and in fixed spatial relation to the housing 9. In this manner, the stabilizer 27 prevents the sensor 14 from moving relative to

the penetrator housing 27 as the catheter flexes or otherwise deforms. In this manner, the stabilizer 27 helps to ensure that the sensor will maintain a substantially constant relationship to the position of the penetrator 20 despite any flexing or bending of the catheter body as may occur in tortuous blood vessels or other curved or constricted anatomical areas.

The example of Figure 3b incorporates the same sensor 14 and stabilizer 11 arrangement as the example shown in Figures 3a-3a', but further includes an imaging apparatus 31 positioned within the catheter 10d. This imaging apparatus 31 may be an intravascular ultrasound (IVUS) transducer, Doppler or any other suitable type of imaging transducer or apparatus. A wire 33 or other communication is provided to transmit image signals from the imaging apparatus 31 to a monitor located outside the patient's body. In this manner, the imaging apparatus 31 may provide an image of anatomical structures located adjacent to or near the catheter tip and such image may be used in conjunction with, merged with or superimposed upon an image of the blood vessel map or scan, such as that shown in Figure 8 and discussed herebelow.

Example Of Double CABG Procedure Performed Using Sensor-Equipped Catheters

Fig. 4 is a schematic illustration of a double coronary artery bypass procedure wherein one tubular bypass graft 40 connects the left internal mammary LIMA to the left anterior descending coronary artery LAD and a second tubular bypass graft 42 connects the descending aorta to the right coronary artery RCA, as shown. These tubular bypass grafts 40, 42 are installed by a percutaneous catheter based procedure as described here above and generally illustrated in Figure 1.

The sensory-equipped vessel wall penetrating catheter of this invention may be used in different ways to accomplish different procedures. Specifically, three general approaches may be employed, namely a) a dual sensor approach wherein one sensor is positioned on the vessel wall penetrating catheter and another sensor is positioned at the target, b) a single sensor approach in a previously sensor-mapped anatomical region and c) a single sensor approach

in an anatomical region for which two-dimensional or three-dimensional data has previously been obtained. Each of these approaches is described in more detail herebelow:

5 A. *A dual sensor approach wherein one sensor is positioned on the vessel wall penetrating catheter and another sensor is positioned at the target*

10 In this embodiment, in addition to the sensor 14 positioned on the vessel wall penetrating catheter 10, a second sensor is positioned at the target location into which the penetrator 20 of the vessel wall penetrating catheter 10 is to extend. Both of these sensors communicate their positions to the computer in real-time (no gating required). The sensor placed at the target location may be mounted on a catheter, such as a mapping catheter, that is advanced transluminally into the target location. This necessarily requires that the target location be a luminal anatomical structure (e.g., a blood vessel) or other
15 anatomical structure having a hollow interior region or a structure within which or on which the second sensor may be placed.

B. A single sensor approach in a previously sensor-mapped anatomical region

20 In this embodiment, a sensor positioned on a mapping catheter is inserted into the anatomical region of interest and the mapping catheter is advanced or moved and the magnetic fields are actuated, so as to provide to the computer with positional data that maps the anatomical structures of interest. Thereafter, after the anatomical structures have been mapped, the mapping catheter may be withdrawn and the vessel wall penetrating catheter 10 having a sensor 14
25 mounted thereon may be inserted. The signals from the sensor 14 of the vessel wall penetrating catheter 10 will then be received by the computer and displayed on a monitor or screen relative to the previously mapped anatomical region. In this manner, the vessel wall penetrating catheter 10 may be positioned and rotationally oriented such that, when the penetrator 20 is subsequently
30 advanced, the penetrator 20 will extend into the desired target location, as shown on the previously mapped anatomical image. Gating may be required if the target location is moving, as would be the case in a beating heart.

C. A single sensor approach in an anatomical region for which two-dimensional or three-dimensional data has previously been obtained

In this embodiment, one or more sensors are placed in or on the patient's body, in fixed position(s) relative to the target location. The anatomical region wherein the target location and sensors are placed is then scanned by a scanning apparatus capable of generating two-dimensional or three-dimensional data that is representative of the of tissues and anatomical configuration/structures within the anatomical region of interest (e.g., a tomographic image generated by Magnetic Resonance Imaging (MRI), Computed Axial Tomography (CT), Spiral CT, Electron Beam CT, ultrasound, etc). After the scan has been completed, the patient is positioned within the sensing field (e.g., on a table close to the magnets or external energy field-creating apparatus used to create the magnetic field(s) of other energy field required for the sensing process to be carried out). The vessel wall penetrating catheter 10 having a sensor 14 mounted thereon or therein is inserted and transluminally advanced to the anatomical region of interest. The vessel wall penetrating catheter's sensor 14 is actuated and provides real-time positional and orientation information to the computer so that the exact position and rotational orientation of the vessel wall penetrating catheter 10 may be determined. The other sensors that had been placed on or in the patients body are also actuated such that they also provide real-time data to the computer and the computer uses such sensor data to position the previously scanned image or anatomical data relative to the sensor positions. In some applications, the sensor(s) placed on or in the patient's body may be imageable, or other imageable marker(s) may be placed on or in the body to indicate on the image the location or intended location of each sensor.

Monitor Display

Figure 8 shows an example of a monitor display that may be generated by any of the above-summarized approaches. In the example of Figure 8, the three-dimensional anatomy of an artery and near-by vein are shown. A sensor-equipped vessel wall penetrating catheter 10 is positioned in the artery. The

sensor 14 on the vessel wall penetrating catheter 10 provides three-dimensional data to the computer. The rotational orientation of the vessel wall penetrating catheter 10 is depicted in a two-dimensional screen insert 30 shown in the lower right corner of the display. A pointer 32 and shows the direction in which the penetrator 20 will advance from the vessel wall penetrating catheter 10. While watching the display, the operator may advance and or retract the vessel wall penetrating catheter 10 until its sensor 14 is in the desired longitudinal position. Thereafter, the operator may look at the two-dimensional insert 30 on the display and may rotate the vessel wall penetrating catheter 10 within the artery until the pointer 32 extends into the vein on the two-dimensional display 30. Thereafter, the penetrator 20 may be advanced out of the vessel wall penetrating catheter 10, through the wall of the artery, through any tissues located between the vein and any artery, through the wall of the vein and into the lumen of the vein, at the desired target location. After this initial penetration has been accomplished, various types of additional procedures may be carried out. In some cases, the penetrator 20 will have a guidewire lumen extending therethrough and a guidewire will be passed through the penetrator lumen and into the vein or other target anatomical structure. Thereafter, the penetrator 20 may be retracted, leaving the guidewire in place. A connector, graft, stent, stent graft or other implantable apparatus may then be advanced over the guidewire and positioned as desire. In some applications, such as those where a channel has been created between two blood vessels, a connector may be disposed in the channel and one or more embolic blockers may be placed in the vessel(s) so as to cause blood to flow from one vessel into the other, as in the catheter-based revascularization procedures (e.g., PICAB™ and/or PICVA™) described in United States Patent Nos. 5,830,222; 6,068,638; 6,159,225 or 6,071,292 or in co-pending United States Patent Application Nos. 08/730,324; 09/117,515; 08/837,295; 09/059,532; 08/837,294, 09/056,589; 09/282,276; 09/282,774 09/505,149 and/or 09/766,502, the entirety of each such patent and patent application being expressly incorporated herein by reference.

***A Percutaneous In Situ Coronary Venous Arterialization (PICVA™)
Procedure Performed Using Sensor-Equipped Catheter(s)***

Figures 6 and 7 show an example of a percutaneous in situ coronary venous arterialization (PICVA™) procedure performed using sensor-equipped catheter(s) of the present invention. In this procedure, vessel 2 has previously been tomographically imaged or has been previously mapped by a sensor-equipped mapping catheter as described hereabove. While the patient is positioned within the sensing field, the sensor-equipped vessel penetrating catheter 10 is advanced into vessel 1 with its sensor 14 actuated, thereby generating a map of the anatomical structure of vessel 1. The computer then compares the anatomical structure of vessel 1 to the anatomical structure of vessel 2 and determines that, in order for the catheter's penetrator 20 to penetrate from the lumen of vessel 1 into the target site 40 located within the lumen of vessel 2, the sensor 14 mounted on the vessel wall penetrating catheter 10 should be positioned at a sensor positioning site 40. Because the sensor 14 is providing real-time positional and rotational data to the operator, the operator is able to advance the vessel wall penetrating catheter 10 through vessel 1 until sensor 14 is positioned at the intended sensor positioning site 42. Thereafter, the operator may rotate the catheter 10 until the rotational orientation of the sensor 14 coincides with the predetermined desired rotational sensor orientation necessary for the penetrator 20 to reach the target location 40. This rotational orientation of catheter 10 may be accomplished with the assistance of the visual rotational orientation display 30 as shown in Figure 8 and described hereabove. After the vessel wall penetrating catheter 10 has been positioned such that its sensor 14 is at the intended sensor location 42 and the rotational orientation of the sensor 14 is such that the penetrator is precisely aimed at the target location 40, the penetrator 20 will be advanced from the vessel wall penetrating catheter 10, outwardly through the wall of vessel 1, through the space between vessel 1 and vessel 2, through the wall of vessel 2 into the lumen of vessel 2 to the target location. Thereafter, a guidewire is advanced through the penetrator 20 and into the lumen of vessel 2 and the penetrator 20 is retracted into the vessel wall penetrating catheter 10. Thereafter, the vessel wall penetrating catheter 10 may be removed from the patient's body. Thereafter, a penetrator tract enlarging apparatus may be advanced over the

guidewire and used to dilate or enlarge the tract created by the penetrator 20. Thereafter a connector may be advanced over the guidewire and deployed in to the channel created between vessel 1 and vessel 2 so as to maintain the approximation of the openings formed in vessel 1 and vessel 2 and to facilitate blood flow between vessel 1 and vessel 2. One or more embolic blockers may be positioned in vessel 1 and/or vessel 2 to facilitate the desired blood flow between vessel 1 and vessel 2. The specific types of channel enlarging apparatus, blocker devices, connector devices and the delivery catheters useable for this purpose are described in United States Patent Nos. 5,830,222; 6,068,638; 6,159,225 or 6,071,292 or in co-pending United States Patent Application Nos. 08/730,327; 09/117,516; 08/970,694 and 09/056,589, the entireties of which are expressly incorporated herein by reference.

When delivering through catheters some types of the connectors and/or blocker devices used in the PICVA™ procedure described above, as well as other types of radially expandable implantable devices (e.g., stents, stent grafts, etc), it may be desirable to utilize a sensor on such delivery catheter to facilitate the desired positioning and rotational orientation of the delivery catheter before deploying the connector, blocker, stent, stent-graft or other implantable device. Figures 9 and 10 show an example of this. In Figures 9 and 10, a partially covered connector 50 having open ends and a sidewall opening 52 is placed in a radially collapsed position within a connector delivery catheter 54. A sensor 14a of the type described hereabove is mounted on or in the delivery catheter 54 in a fixed longitudinal position and fixed rotational orientation relative to the rotational orientation of the catheter-mounted connector device 50. In the manner described hereabove with respect to the vessel wall penetrating catheter 10, the precise longitudinal position and rotational orientation of the connector delivery catheter 54 may be determined prior to deployment of the connector 50 from the catheter 54. The ability to precisely determine the rotational orientation of the delivery catheter 54 will allow the side opening 52 of the connector 50 to be pre-positioned before deployment of the connector 50 such that, when the connector 50 is subsequently deployed from the catheter 54 and allowed to radially expand, its side opening 52 will be in the desired location relative to the

patient's anatomy. This is specifically illustrated Figure 10, where a channel has been created between an artery and a vein using a vessel wall penetrating catheter 10, as described hereabove and shown in Figures 7, 8 and 11. After the channel has been enlarged, a connector delivery catheter 54 of the type shown in Figure 9, having a radially collapsed blocker 50 positioned therein, is advanced over the pre-positioned guidewire. The connector delivery catheter 54 is advanced until the longitudinal position of its sensor 14a, as determined by the computer and shown on display, indicates that the connector 50 is positioned within the previously created the vein-artery channel with the opposite ends of the connector 50 disposed in the artery and vein, respectively. Thereafter, the connector delivery Catheter 54 is rotated until the rotational position of the sensor 14a indicates that the side opening 52 of the connector 50 is a pat the desired location. Thereafter, the sheath 56 of the connector delivery catheter 54 is withdrawn in the proximal connection, thereby removing the surrounding constraint from the radially compact connector 50 and allowing the connector 50 to radially expand and become implanted in the position shown in Figure 10. In such position, some of the arterial blood which enters the end of the connector 50 positioned within the artery may pass-through the side opening 52 and continue to flow through the artery, while the remainder of the arterial blood would diverge through the lumen of the connector 50 and out of its opposite end located within the vein.

Sensor-Equipped Anchorable Sheath

Figures 12-12b show an example of a sensor-equipped anchorable sheath 100 of this invention, and Figure 12 c shown a cross section of a specially designed penetrating catheter that is useable in conjunction with the sensor-equipped anchorable sheath 100.

The sheath 100 comprises a handpiece or hub 102 and an elongate, flexible sheath body 104 having a side aperture 106 formed in its side wall near its distal end. An anchoring balloon 108 is positioned on the side wall of the sheath, 100 diametrically opposite its side aperture 106. At least one sensor 108 is mounted in the distal portion of the sheath body 104 and a wire 110

extends through a blind lumen 112 to connect the sensor to the extracorporeal sensing and control equipment described elsewhere in this application. It will be appreciated that, alternatively to the single sensor embodiment shown, two or more sensors 108 may be positioned at two or more locations in or on the sheath body 104. A guidewire lumen 114 extends longitudinally through the sheath 100 to permit it to be advanced over a guidewire in accordance with well known and established operational technique. A working lumen 116 extends through the sheath body 104 at least to the location of the side aperture 106 such that a separate catheter, such as a tissue penetrating catheter 120 (Figure 12c) may be advanced into the working lumen 116 to a position adjacent to the side aperture 106. The working lumen is non-round in cross section, keyed, serrated or otherwise configured such that when the catheter 120 is inserted into the working lumen 116 the catheter 120 will not rotate.

In one mode of operation, the sensor-equipped sheath may be inserted and advanced through the vasculature to a position that is near or adjacent to a target location (e.g., a location within the lumen of another blood vessel, a location within tissue, an anatomical structure, a tumor, etc.). In the manner described above, the sensor 108 may be used to longitudinally and rotationally position the sheath such that its side aperture 106 is directed at and aligned with the target location. The anchoring balloon 108 is then inflated to anchor the sheath body 104 in fixed longitudinal and rotational position within the vessel. Thereafter, a catheter or elongate device, such as a penetrating catheter 120 is inserted into the working lumen 116 in a known rotational orientation. The catheter 120 is then advanced to a position where its penetrator outlet port (not shown in Figure 12c) is within the side aperture 106. The penetrator 20a may then be advanced through the side aperture 106 and to the target location. In this manner, the sheath 100 is used to guide the specific position and orientation of the penetrating catheter 120, and the penetrating catheter is non-rotatably advanced through the working lumen 116 of the sheath such that the penetrating catheter 120 must remain in fixed rotational orientation relative to that of the pre-positioned and anchored sheath body 104.

It is to be appreciated that the invention has been described hereabove

with reference to certain examples or embodiments of the invention but that various additions, deletions, alterations and modifications may be made to those examples and embodiments without departing from the intended spirit and scope of the invention. For example, any element or attribute of one embodiment or example may be incorporated into or used with another embodiment or example, unless to do so would render the embodiment or example unsuitable for its intended use. Also, it is to be understood and appreciated that the magnetic sensors and related apparatus described above may be replaced with or interchanged with other types of sensors and sensing apparatus (e.g., radiofrequency, other magnetic sensors, ultrasound, microwave, light, x-ray, etc) that are useable for the intended purpose. All such reasonable additions, deletions, modifications and alterations are to be considered equivalents of the described examples and embodiments and are to be included within the scope of the following claims.

15

CLAIMS

What is claimed is:

1 1. A navigable tissue penetrating catheter system comprising:
2 a field generator for generating a sensing field about at least a portion of
3 the body of a human or veterinary patient;
4 a tissue penetrating catheter comprising a) a catheter body, b) a
5 penetrator that is advanceable from the catheter body so as to penetrate
6 outwardly through the wall of an anatomical conduit in which the catheter body
7 is positioned to a target location and c) a sensor located on or in the catheter
8 body in known positional relation to the penetrator, for sensing components of
9 the sensing field and emitting signals indicative of the position and/or rotational
10 orientation of the sensor within the sensing field; and,
11 a sensor monitor which receives signals from the sensor and provides, on
12 the basis of those signals, a prediction of the path upon which the penetrator will
13 advance from the catheter.

1 2. A navigable tissue penetrating catheter system according to Claim
2 1 wherein the field generator comprises at least one apparatus selected from the
3 group consisting of:
4 at least one magnetic apparatus for creating a magnetic sensing field;
5 at least one ultrasound generating device for creating an ultrasonic
6 sensing field;
7 at least one infrared apparatus for generating an infrared sensing field;
8 at least one x-ray device for creating an x-ray field;
9 at least one light-emitting device for creating a light energy field;
10 at least one microwave device for creating a microwave field;
11 at least one radiofrequency device for creating a radiofrequency field;
12 at least one microcurrent device for generating a microcurrent sensing
13 field; and,
14 possible combinations thereof.

1 3. A navigable tissue penetrating catheter system according to Claim
2 1 wherein the sensor is mounted on or in the catheter body in fixed longitudinal
3 position and fixed rotational orientation relative to the trajectory on and/or
4 direction in which the penetrator will advance from the catheter body, thereby
5 enabling the operator to use the indicia provided by the processing and indicia-
6 providing means to position and rotationally orient the catheter within the
7 patient's body such that, when the penetrator is subsequently advanced from the
8 catheter body, the penetrator will penetrate outwardly through the wall of the
9 anatomical conduit in which the catheter body is positioned and to the target
10 location.

1 4. A system comprising a navigable tissue penetrating catheter
2 according to Claim 1 further in combination with a sensor-equipped mapping
3 catheter, said sensor-equipped mapping catheter comprising an elongate,
4 flexible catheter body having a sensor positioned on or in the catheter body, said
5 mapping catheter being movable through the target location such that the sensor
6 of the mapping catheter may be used to obtain data points mapping the target
7 location or to act as a marker of the target location.

1 5. A system according to Claim 4 wherein the mapping catheter
2 further comprises a centering apparatus for centering a portion of the mapping
3 catheter in or on which the sensor is located within an anatomical conduit.

1 6 A system according to Claim 5 wherein the centering apparatus
2 comprises a centering balloon.

1 7. A system according to Claim 4 wherein the centering apparatus
2 comprises a plurality of centering arms that deploy from the mapping catheter
3 body to center said portion of the mapping catheter within the anatomical
4 conduit.

1 8. A method for using a navigable tissue penetrating catheter system

2 in a human or veterinary patient to penetrate from a location within the lumen of
3 a luminal anatomical conduit that has a wall, outwardly through the wall of the
4 anatomical conduit and to a target location, said method comprising the steps
5 of:

- 6 (A) providing a navigable tissue penetrating catheter system
7 comprising i) a field generator for generating a sensing field about
8 at least a portion of the body of a human or veterinary patient; ii)
9 a tissue penetrating catheter comprising a) a catheter body, b) a
10 penetrator that is advanceable from the catheter body so as to
11 penetrate outwardly through the wall of an anatomical conduit in
12 which the catheter body is positioned to a target location and c) a
13 sensor mounted on or in the catheter body for sensing
14 components of the sensing field and emitting signals indicative of
15 the position and/or rotational orientation of the sensor within the
16 sensing field; and, iii) a sensor-monitor adapted to receive signals
17 from the sensor and to provide, on the basis of those signals,
18 indicia of the position and/or rotational orientation of the sensor
19 within the sensing field.
- 20 (B) using the field generator to create a sensing field;
- 21 (C) positioning at least the portion of the patient's body in which the
22 target location is located within the sensing field;
- 23 (D) inserting the tissue penetrating catheter into the patient's body and
24 advancing the catheter into an anatomical conduit located within
25 the sensing field;
- 26 (E) actuating the sensor of the tissue penetrating catheter such that
27 signals from the sensor are received by the sensor monitor;
- 28 (F) using the indicia provided by the sensor monitor to position and/or
29 rotationally orient the catheter body within the anatomical conduit
30 such that, when the penetrator is subsequently advanced from the
31 catheter body, it will penetrate outwardly through the wall of the
32 anatomical conduit in which the catheter body is positioned and to
33 the target location; and,

34 (G) advancing the penetrator from the catheter body, through the wall
35 of the anatomical conduit in which the catheter body is positioned
36 and to the target location.

1 9. A method according to Claim 8 wherein the anatomical conduit in
2 which the catheter body is positioned is an artery; vein; urethra; ureter; fallopian
3 tube; esophagus; trachea; lymphatic; nasal passage; GI tract; chamber of the
4 heart; ventricle of the brain or a man made interstitial space, channel, tunnel or
5 pocket.

1 10. A method according to Claim 8 wherein the target location is
2 selected from the group consisting of:
3 an artery;
4 a vein;
5 a location within the parenchyma of an organ;
6 a cavity within an organ;
7 a body cavity;
8 an aberrant anatomical structure
9 an anatomical malformation;
10 a location to which a drug, substance, flow of energy or apparatus
11 is to be delivered; and,
12 a location from which a sample, reading, image or diagnostic
13 information is to be obtained.

1 11. A method according to Claim 8 further comprising the steps of:
2 providing a sensor-equipped mapping catheter; and,
3 using the sensor equipped mapping catheter to map or mark the target
4 location.

1 12. A method according to Claim 11 further comprising the step of:
2 displaying the map of the target location to the operator.

1 13. A method according to Claim 12 wherein the map of the target
2 location is displayed by the sensor monitor along with the indicia
3 received from the sensor of the tissue penetrating catheter.

1 14. A method according to Claim 8 further comprising the steps of:
2 positioning a body-mounted sensor in or on the patient's body in a known
3 positional relationship to an anatomical landmark,
4 obtaining a three dimensional scan of at least the portion of the patients
5 body in which the body-mounted sensor and the target location are located;
6 displaying the three dimensional scan to the operator; and,
7 actuating the body-mounted sensor during performance of Steps F-G of
8 the method, thereby enabling the operator to discern the position the body-
9 mounted sensor and to ascertain the position of the target location within the
10 sensing field on the basis of the previously obtained three dimensional scan.

1 15. A navigable delivery catheter system for delivering a radially
2 expandable implantable device to a target location within the body of a human
3 or veterinary patient, said system comprising:
4 a field generator for generating a sensing field about at least a portion of
5 the body of the patient, said sensing field comprising field components that are
6 detectable by a sensor;
7 a delivery catheter comprising a) a catheter body and b) a sensor
8 mounted on or in the catheter body sensing components of the sensing field and
9 emitting signals indicative of the position and/or rotational orientation of the
10 sensor within the sensing field;
11 an implantable article mounted in or on the delivery catheter and
12 deployable from the catheter such that it separates from and is free of the
13 catheter body; and,
14 a signal monitor which receives signals from the sensor and provides, on
15 the basis of those signals, indicia of the position and/or rotational orientation of
16 the sensor within the sensing field.

1 16. A navigable delivery catheter system according to Claim 15
2 wherein the field generator comprises one or more field generating apparatus
3 selected from the group consisting of:

4 at least one magnet for creating a magnetic sensing field;
5 at least one ultrasound generating device for creating an ultrasonic
6 sensing field;
7 at least one infrared apparatus for generating an infrared sensing field;
8 at least one x-ray device for creating an x-ray field;
9 at least one light-emitting device for creating a light energy field;
10 at least one microwave device for creating a microwave field;
11 at least one radiofrequency device for creating a radiofrequency field;
12 at least one microcurrent device for generating a microcurrent sensing
13 field; and,
14 possible combinations thereof.

1 17. A navigable delivery catheter system according to Claim 15
2 wherein the implantable article comprises a radially expandable implantable
3 device.

1 18. A navigable delivery catheter system according to Claim 17
2 wherein the radially expandable implantable device comprises a stent.

1 19. A navigable delivery catheter system according to Claim 17
2 wherein the radially expandable implantable device comprises stent-graft.

1 20. A navigable delivery catheter system according to Claim 17
2 wherein the radially expandable implantable device comprises a connector that
3 is implantable between openings formed in the walls of two blood vessels to
4 maintain a blood flow channel between the blood vessels.

1 21. A navigable delivery catheter system according to Claim 17
2 wherein the radially expandable implantable device comprises a radially

3 expandable tube graft.

1 22. A navigable delivery catheter system according to Claim 16
2 wherein the implantable article comprises a substance delivery device.

1 23. A method for using a navigable delivery catheter system to implant
2 a radially expandable, implantable device in a predetermined rotational
3 orientation at a target location within the patient's body, said method comprising
4 the steps of:

- 5 (A) providing a navigable delivery catheter system that comprises i)
6 a field generator for generating a sensing field about at least a
7 portion of the body of the patient, said sensing field comprising
8 field components that are detectable by a sensor; ii) a delivery
9 catheter comprising a) a catheter body and b) a sensor mounted
10 on or in the catheter body sensing components of the sensing field
11 and emitting signals indicative of the position and/or rotational
12 orientation of the sensor within the sensing field; iii) a radially
13 expandable implantable device mounted in or on the delivery
14 catheter in a radially collapsed configuration and deployable from
15 the catheter such that it will assume a radially expanded
16 configuration free of the catheter body; and, iv) a signal monitor
17 which receives signals from the sensor and provides, on the basis
18 of those signals, indicia of the position and/or rotational orientation
19 of the sensor within the sensing field.
- 20 (B) using the field generator to create a sensing field;
- 21 (C) positioning at least the portion of the patient's body in which the
22 target location is located within the sensing field;
- 23 (D) inserting the navigated delivery catheter with the radially
24 expandable device mounted thereon or therein, into the patient's
25 body and advancing it into an anatomical conduit located within
26 the sensing field;
- 27 (E) actuating the sensor mounted on or in the catheter body such that

- 28 signals from the sensor are received by the sensor monitor;
29 (F) using the indicia provided by the sensor monitor to position the
30 catheter at the target location and/or to rotationally orient the
31 catheter such that, when the radially expandable device is
32 subsequently deployed from the catheter it will assume its radially
33 expanded configuration and will become implanted at the target
34 location in the desired rotational; and,
35 (G) deploying the radially expandable implantable device from the
36 delivery catheter such that it radially expands and becomes
37 implanted at the target location in the desired rotational orientation.

1 24. A navigable catheter system according to Claims 1 or 15 wherein
2 the sensor mounted on the catheter comprises an an emitter or transmitter and
3 the sensor monitor comprises at least one detector capable of detecting signals
4 from the emitter or transmitter and determining the 3 dimensional position and/or
5 rotational orientation of the catheter within the patient's body.

1 25. A navigable tissue penetrating catheter system according to Claim
2 1 or 15 wherein the sensor is positioned on the catheter body.

1 26. A navigable tissue penetrating catheter system according to Claim
2 1 or 15 wherein the sensor is positioned on the tissue penetrator.

1 27. A navigable tissue penetrating catheter system according to Claim
2 1 or 15 wherein the sensor is positioned on an apparatus that is inserted through
3 or into the catheter.

1 28. A navigable tissue penetrating catheter system according to Claim
2 27 wherein the sensor is positioned on a guidewire that is insertable into or
3 through the catheter.

1 29. A navigable tissue penetrating catheter system according to Claim

1 1 or 15 wherein the sensing field and the sensor monitor are adapted to propel
2 the catheter body, penetrator or a device that has been inserted through or
3 around the tissue penetrator, to a specific 3-dimensional location within the
4 patient's body.

1 30. A navigable tissue penetrating catheter system according to Claim
2 1 or 15 wherein the sensing field and the sensor monitor are adapted to propel
3 the catheter body, penetrator or a device that has been inserted through or
4 around the tissue penetrator, to a specific rotational orientation within the
5 patient's body.

1 31. A navigable tissue penetrating catheter system according to Claim
2 1 or 15 wherein the sensor is mounted in substantially fixed spacial relation to
3 the penetrator.

1 32. A navigable tissue penetrating catheter system according to Claim
2 31 wherein the penetrator is initially positioned in a penetrator housing within the
3 catheter and wherein the sensor is attached to the penetrator housing such that
4 the penetrator housing and sensor are maintained in substantially fixed spacial
5 relation to one another.

1 33. A navigable tissue penetrating catheter system according to Claim
2 1 or 15 further comprising an imaging apparatus for imaging anatomical
3 structures.

1 34. A navigable tissue penetrating catheter system according to Claim
2 33 further comprising a monitor for displaying an image received from the
3 imaging apparatus along with an indication of the sensor position within the
4 sensing field.

1 35. A navigable tissue penetrating catheter system according to Claim
2 33 wherein the inaging apparatus comprises an intravascular ultrasound imaging

3 transducer.

1 36. A sensor-equipped sheath for guiding the insertion of an elongate
2 catheter or apparatus said sensor-equipped sheath comprising:
3 an elongate, flexible, tubular sheath body having a side wall and at least
4 one lumen extending longitudinally through at least a portion thereof;
5 a side aperture formed in the side wall of the sheath body and
6 communicating with the lumen of the sheath;
7 an anchoring apparatus for anchoring the portion of the sheath body
8 wherein the side aperture is located in a substantially fixed position within the
9 lumen of a body conduit;
10 a rotation inhibiting surface associated with the sheath lumen such said
11 rotation inhibiting surface engages an elongate catheter or apparatus that has
12 been inserted into the sheath lumen and advanced to a position adjacent the
13 side aperture, thereby preventing the catheter or apparatus from undergoing
14 substantial rotational movement relative to the sheath.

1 37. A sensor-equipped sheath according to Claim 36 having a plurality
2 of said sensors.

1 38. A sensor-equipped sheath according to Claim 36 wherein the
2 anchoring apparatus comprises an inflatable balloon.

1 39. A system comprising a sensor-equipped sheath according to Claim
2 36 in combination with an elongate catheter or apparatus that is insertable into
3 the sheath lumen and advanced to a position adjacent the side aperture, said
4 elongate catheter or apparatus being configured such that it engages the rotation
5 inhibiting surface and is thereby prevented from undergoing substantial
6 rotational movement relative to the sheath.

1 40. A system according to Claim 39 wherein the elongate catheter or
2 apparatus comprises a tissue penetrating catheter having an elongate catheter
3 body configured to engage the rotation inhibiting surface and a tissue penetrator

- 4 that is advanceable through the side aperture of the sheath.

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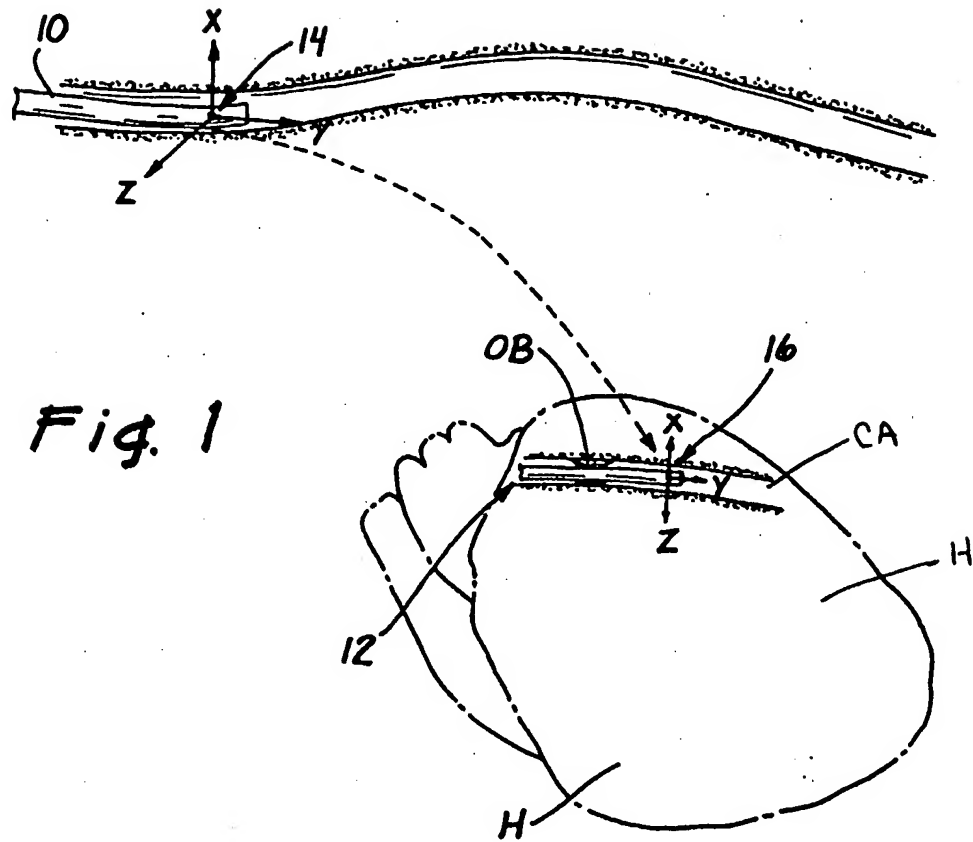
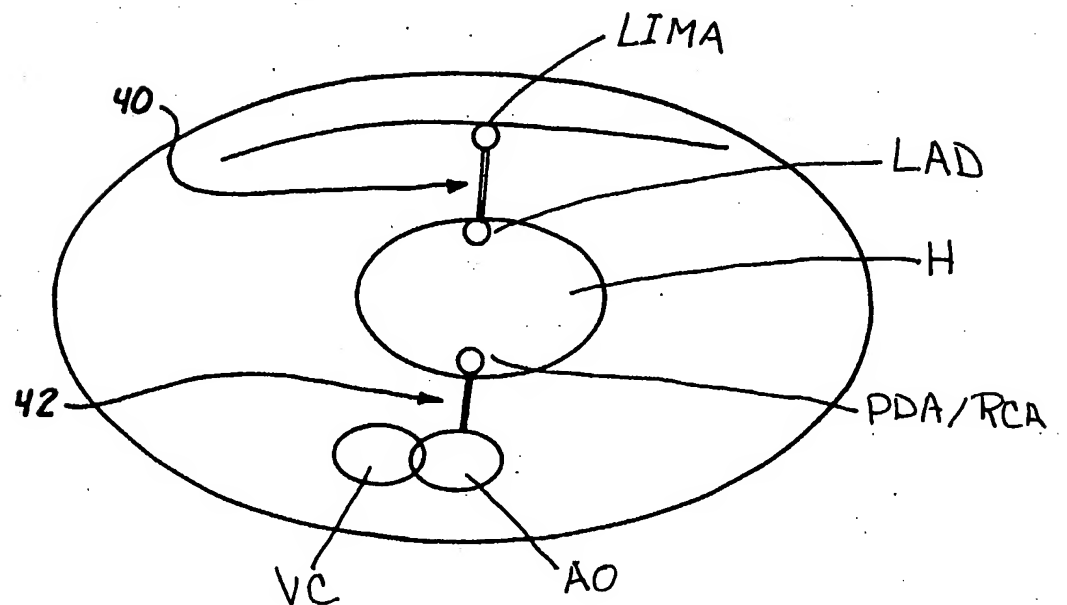
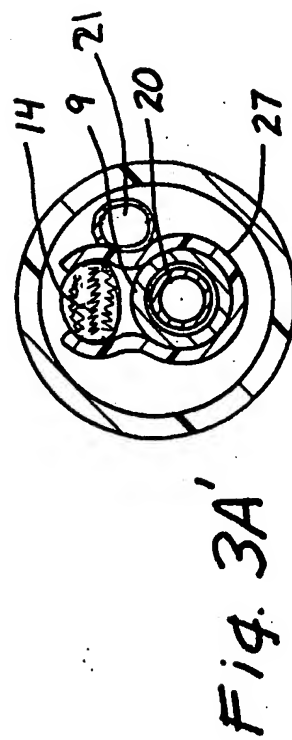
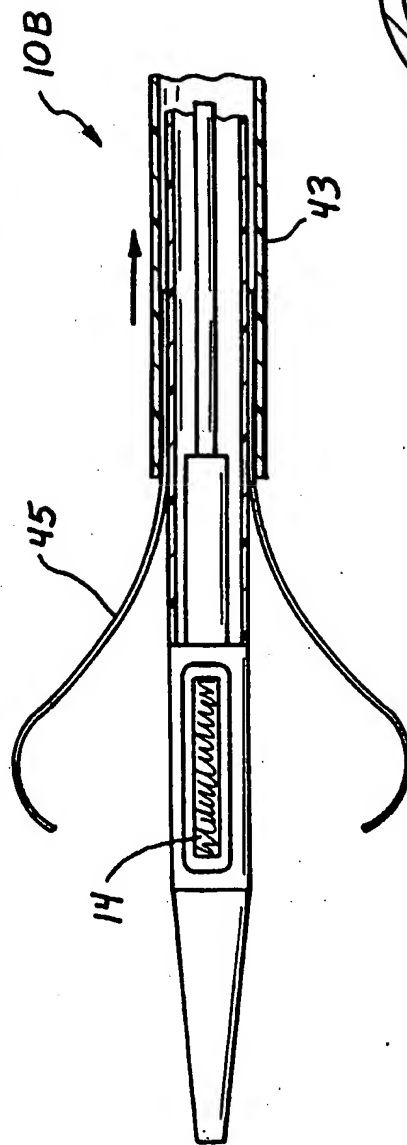
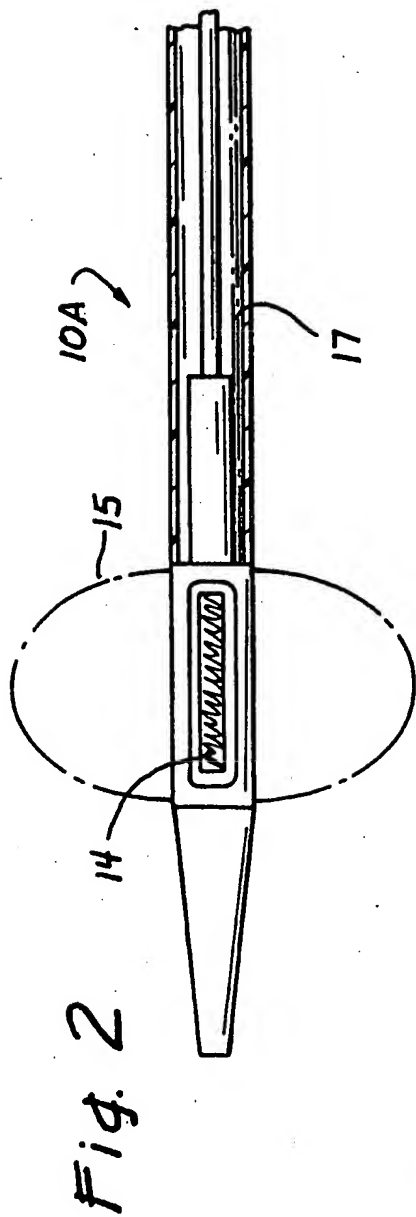


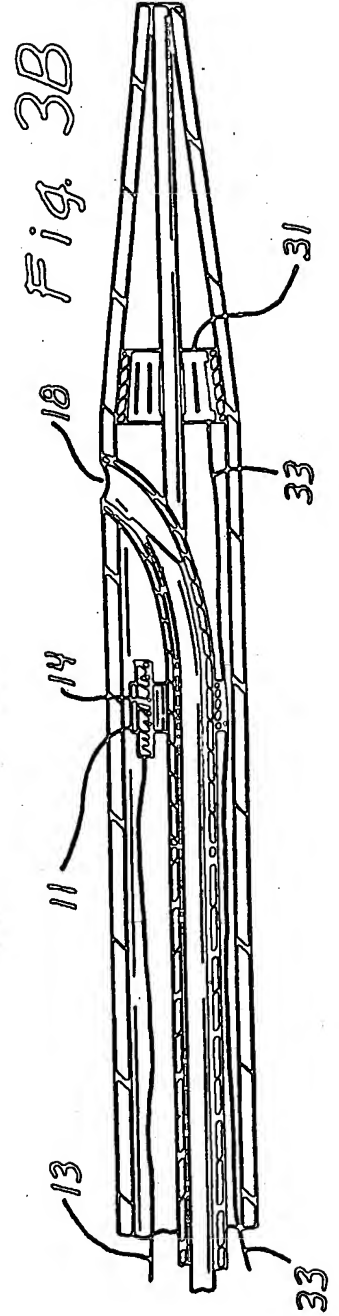
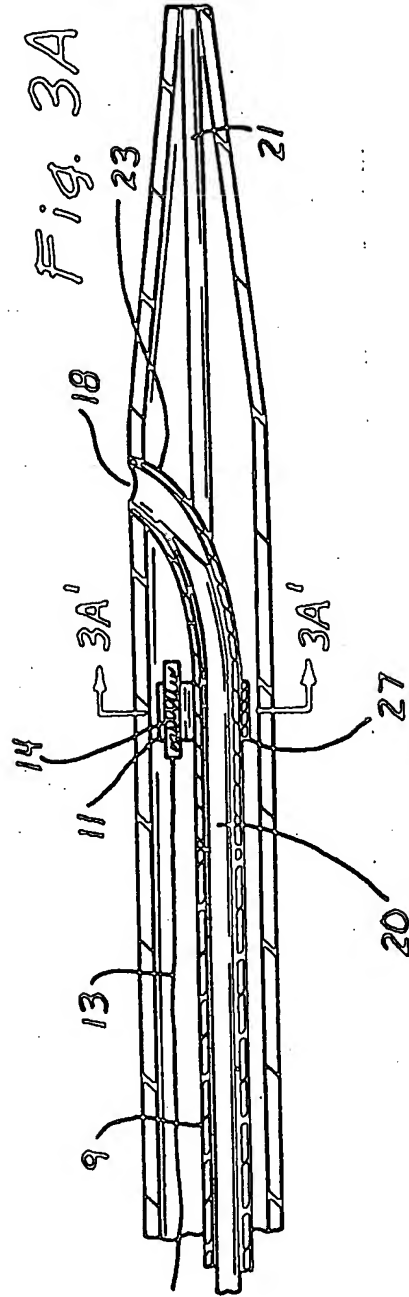
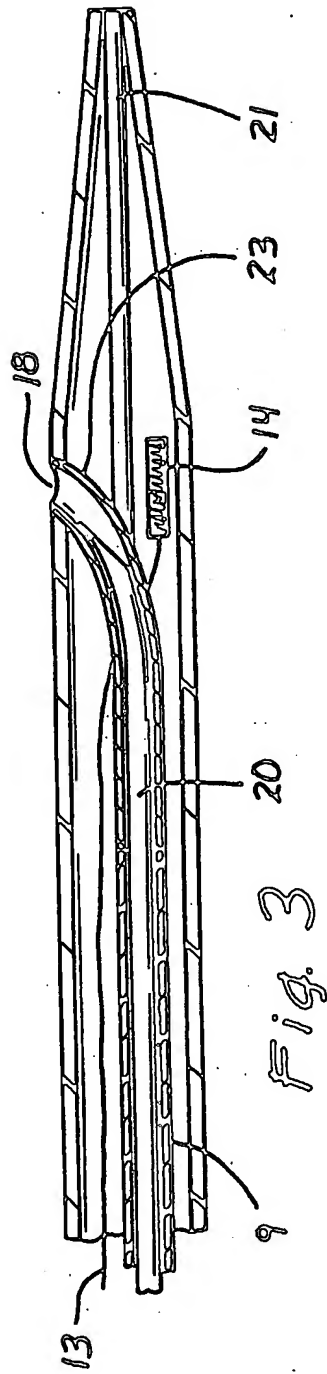
Fig. 4



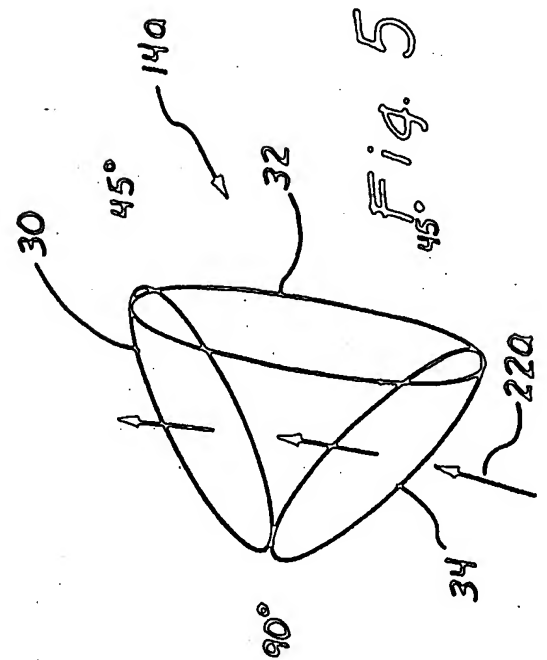
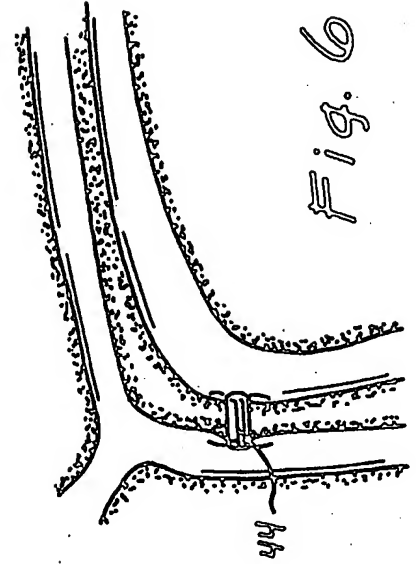
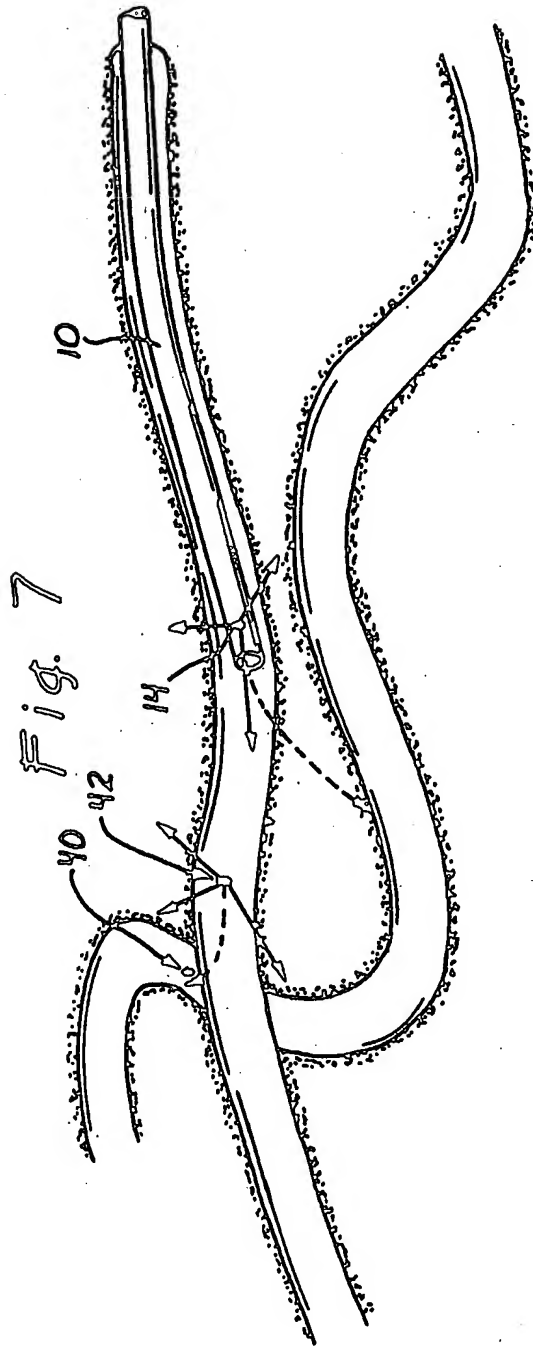
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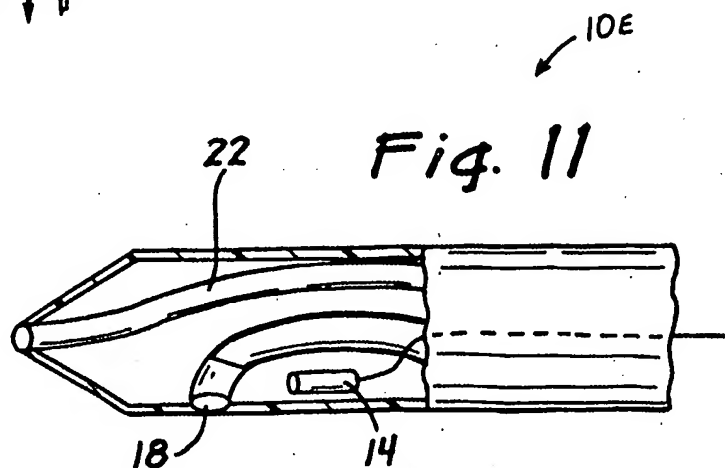
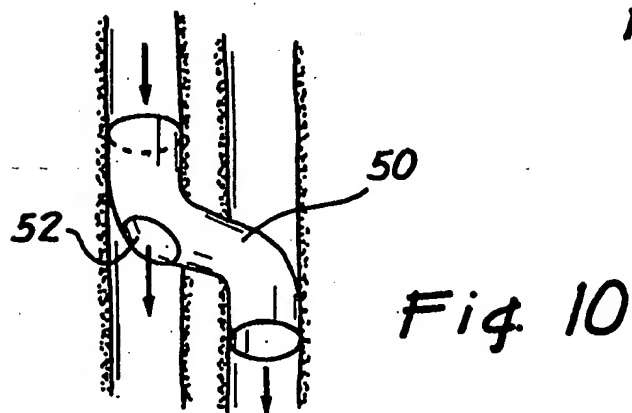
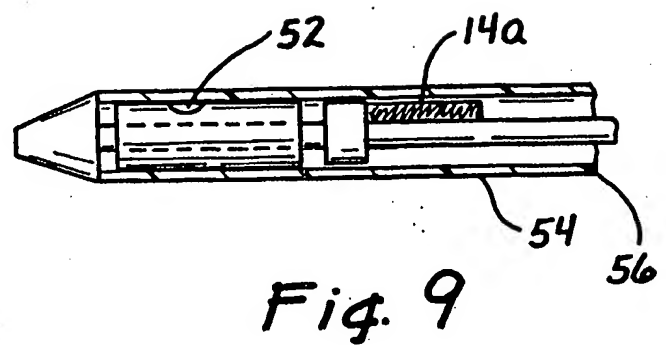
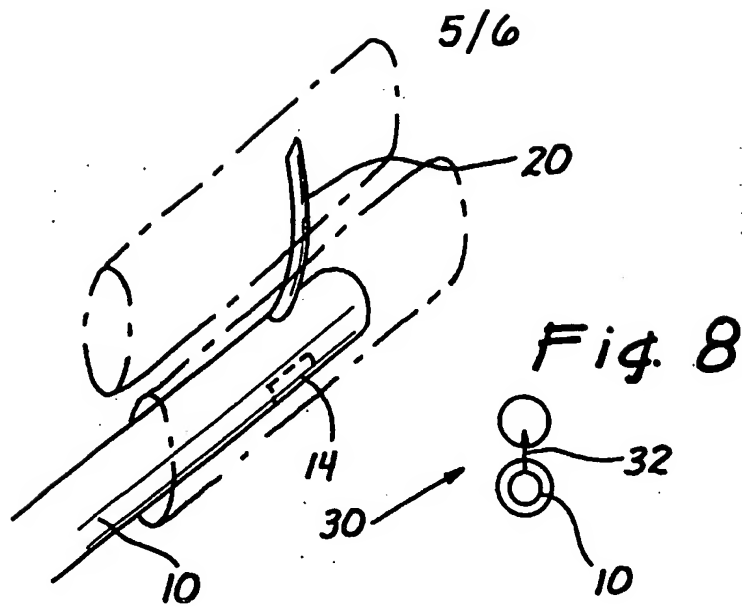


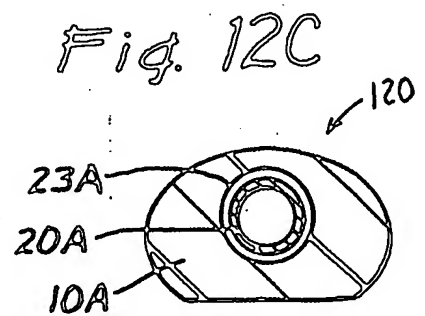
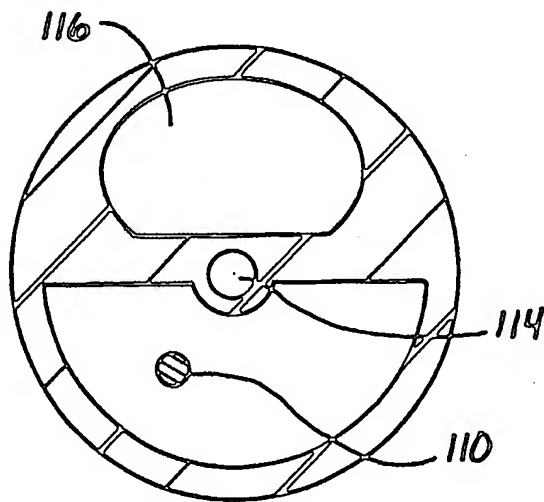
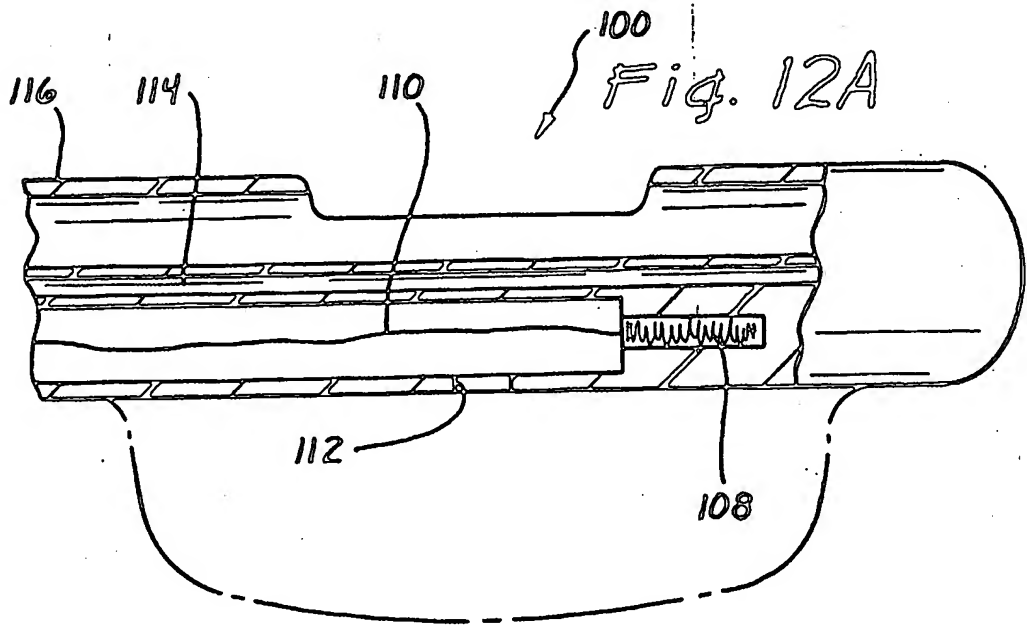
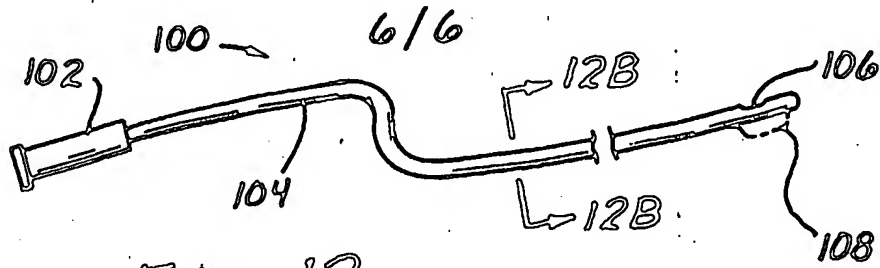
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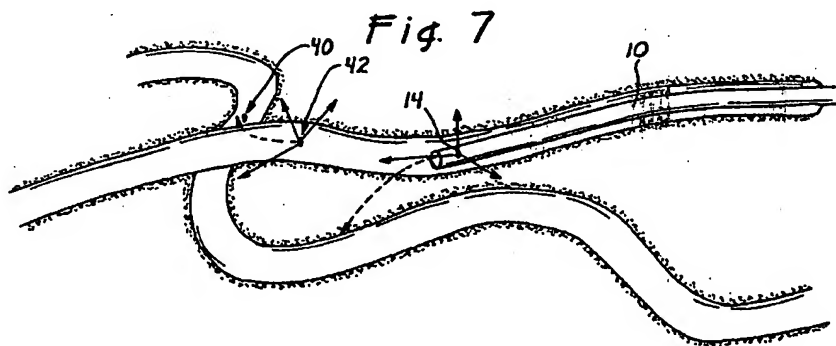
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(54) Title: METHODS AND APPARATUS FOR GUIDED TRANSLUMINAL INTERVENTIONS USING VESSEL WALL PENETRATING CATHETERS AND OTHER APPARATUS



(57) Abstract: Electro-anatomically navigated catheters (10) (e.g., mapping catheters, tissue penetrating catheters, delivery catheters and/or sheaths) and associated methods whereby devices or substances may be delivered to specific locations within a patient's body and/or penetration tracts (20) or passageways are formed at specific locations between anatomical structures. The catheters are equipped with sensors (14) and a sensing field is created around the body of the patient. The sensor-equipped catheters are then inserted into the patient's body and the position of the catheter-mounted sensor(s) is/are observed on a display representing the sensing field. Apparatus may be included for propelling the catheter(s) to specific locations and/or specific rotation orientations, within the patient's body.

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Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 6,004,269 A (CROWLEY et al.) 21 December 1999 (21/12/1999), entire document.	1-40
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